

## **REMARKS**

### ***Status of Claims***

Claims 6, 9-12, 18, 19, 21-29, 38, 45-48, 50, and 52-75 are pending.

Claims 6, 9, 10, 12, 22, 23, 29, 38, 45, 48, 52, 54, 55, 57, 60, 61, 63, 66, 67, 69, 70, and 75 are amended herein. Claims 76-81 are newly presented. Claims 28 and 65 are cancelled herein without prejudice.

All claims find support in the specification as originally filed. More specifically, support for “*companion*” and “*farm*” animal is found at least at page 22, lines 25-28.

No new matter is introduced.

Applicants reserve the right to reintroduce cancelled subject matter, for example, in a later-filed continuing application.

### ***Objection to the Specification***

As requested by the Office, by the present amendment to the Specification, the embedded hyperlink and/or browser-executable code at page 10, line 6 is cancelled. Office Action at page 2.

Withdrawal of the rejection is respectfully requested.

### ***Rejection of Claims under 35 U.S.C. §112, 1<sup>st</sup> paragraph is Rendered Moot***

The Office rejected claims 6, 9-11, 18, 19, 21, 38, 52-54, 56-59, and 69-75 as allegedly failing to comply with the written description requirement. Office action at pages 2-6.

The Office states that:

In view of a lack structure to function correlations for *parts* of gp 120 in receptor binding as well as for *a part or variant* of an antigen in the instant specification and the lack of predictability as taught by the prior art in such protein structure to function correlations, the claims are rejected as lacking written description.

Office Action at page 5, line 20 through page 6, line 2; Emphasis in original.

Applicants respectfully disagree with the Office assertion regarding alleged lack of written description. Nonetheless, solely for the purpose of advancing prosecution, the terms “parts thereof” and “part or variant of such a molecule” are cancelled by the present amendment to the claims.

In view of the foregoing amendment, the rejection is rendered moot. Withdrawal of the rejection is respectfully requested.

***Rejection of Claims under 35 U.S.C. §102(b) is Traversed or Rendered Moot***

The Office rejected claims 6, 9-11, 18, 18, 38, 52-54, 56, 57, and 69-72 as allegedly anticipated by Patterson *et al.*, (*Biochem. and Biophys. Res. Com.* [285(3):639-43] 2001 (“Patterson”). Office Action at pages 6-7. In view of the foregoing amendment and the following remarks, the rejection is traversed or rendered moot.

The Office states that:

Patterson *et al.* describe a hybrid protein comprising hepatitis B core antigen linked to the amino end of large fragment of gp120 ...

HBcAg is associated with a disease and a pathogen, wherein the pathogen is a virus, meeting limitations of claims 9-11 and 71.

To establish anticipation, “the reference must teach each and every element of the claim.” MPEP §2131. However, Patterson fails to disclose hepatitis B core antigen (HBcAg) sequence linked to a *full length* gp120. See, *e.g.*, Patterson at page 640, Figure 1. As can be seen by the present amendment to the claims, the term “or parts thereof” relating to gp120 is cancelled, therefore, *full length* gp120 is a required feature of the claimed invention.

For at least the foregoing reason, Patterson could not possibly have anticipated Applicants’ claimed invention. Accordingly, withdrawal of the rejection is respectfully requested.

Additionally, Applicants note that Patterson fails to disclose an antigen associated with a disease of a *companion* or *farm* animal. Patterson states that “[h]epatitis B core antigen is a potent immunogen in man.” Patterson at page 639, left column, last three lines. As can be seen by the present amendment, the claims require: “*the antigen is a molecule associated with a disease of the companion animal or the farm animal*” (claim 6); “*the antigen is an antigenic component of a tumor or a pathogen of the companion*

*animal or the farm animal*" (claim 52); or *"a disease-associated polypeptide of a companion animal or a farm animal"* (claim 69). Further, Applicants note that new claims 79-81 require that the companion or farm animal is selected from the group consisting of cow, sheep, horse, pig, goat, dog, cat and rabbit. Thus, for this reason also, Patterson could not possibly have anticipated Applicants' claimed invention.

Accordingly, Applicants respectfully request that the rejection of claims 6, 9-11, 18, 18, 38, 52-54, 56, 57, and 69-72 be withdrawn.

***Rejection of Claims under 35 U.S.C. §103(a) is Traversed or Rendered Moot***

The Office rejected claims 19, 21, 58, 59, and 73-75 as allegedly obvious over Patterson, and further in view of Hancock et al. (Vaccine, [19:4874-4882] 2001) ("Hancock"). Office Action at pages 7-9. In view of the foregoing amendment and the following remarks, the rejection is traversed or rendered moot.

The Examiner states that:

Patterson et al. does not teach using adjuvants (claims 19 and 58), pharmaceutical carriers (claims 21 and 59) and using an F protein derived from RSV as the antigen (claims 73-75).

Hancock et al. disclose using potent adjuvants in combination with an F protein of RSV as vaccines ... The authors vaccinated mice with a composition comprising an F protein and PBS in the presence or absence of CpG containing sequences ...

It would have been obvious ... to further use adjuvants for the advantage of amplifying an immune response (see Table 1 of Hancock et al.).

Office Action at page 8, line 16 through page 9, line 10.

Applicants restate the discussion above as it relates to Patterson. The additional secondary reference cited here, namely Hancock, is set forth as allegedly providing only the element of further dependent claims 19, 21, 58, 59, and 73-75. Hancock is not set forth as curing the noted deficiencies of Patterson as discussed above. It is believed that Hancock does not cure the noted deficiencies of Patterson as noted herein.

Accordingly, for at least the foregoing reason, the Office has not satisfied its burden of establishing a *prima facie* case of obviousness against the claimed invention. Applicants respectfully request that the rejection be withdrawn and that the claims be allowed.

Additionally, or in the alternative, Applicants note that before the Office can be deemed to have satisfied its burden of establishing a *prima facie* case of obviousness against the claimed invention, all elements of the claims must be shown in the combination of cited references or the Office must provide an explanation for why those elements are supplied by some other means, *i.e.*, why the claimed subject matter has been clearly suggested. See *In re Wright*, 343 F.2d 761, 145 USPQ 182 (CCPA 1965). As illustrated below, the Office has not asserted that the combined references provide or clearly suggest all elements of the claimed invention.

According to the Office, “Hancock et al. disclose using potent *adjuvants* in combination with an F protein of RSV as vaccines.” Office Action at page 8, lines 19-20; Emphasis added. However, the Office has not given any reasons why the skilled person would replace the Hepatitis core antigen component of the compounds in Patterson with the F protein of RSV of Hancock. Neither one of the references suggests that the F protein of RSV would have any effect on the immunogenicity of gp120. Since Patterson only included the Hepatitis core antigen in the HIV gp120 hybrid to enhance the immunogenicity of the gp120, and there is no statement, suggestion or indication that the F protein of RSV might have this ability, the Office fails to establish a *prima facie* case that the skilled person would have any motivation or reason to combine Patterson with Hancock to arrive at the claimed invention. Indeed, Hancock describes that using oligonucleotides containing unmethylated CpG motifs (CpG ODN) as an adjuvant increased the immunogenicity of the F protein vaccine. Thus, if the skilled person would have combined the teachings of Hancock with Patterson, the skilled person would at best have used an adjuvant as described by Hancock as improving immunogenicity, *e.g.*, the CpG ODN adjuvant, and not the F protein, to enhance the immunogenicity of the gp120 vaccines as described by Patterson. The combination of these two documents would direct the skilled person away from the claimed invention.

For at least these reasons, the rejection is in error and must be withdrawn.

Accordingly, Applicants respectfully request that the rejection be withdrawn.

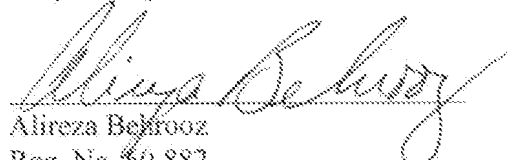
**CONCLUSIONS**

The claims are now in condition for examination and allowance.

If the Office has any questions regarding this submission, the Examiner is invited to contact Applicants' undersigned representative using the information provided below.

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Respectfully submitted,



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